

REMARKS

Claims 1-3, 5-9, 18, 28 and 29 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite. Claims 1-29 stand rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter. Claims 1-29 stand rejected under 35 U.S.C. 103(a) as being obvious over Short et al in view of Sitka et al and Hilton. In view of the present amendments and for the following reasons, the Examiner is respectfully requested to reconsider the rejection of record and allow the present application to issue.

Indefiniteness under 35 U.S.C. 112, Second Paragraph

The Examiner's identification of the lack of antecedent for "said super orders" in the sixth paragraph of claim 18 is most appreciated. This defect has been corrected by the present amendment.

With regard to claim 28, the present amendment is presented to clarify that a combination is being claimed. The combination includes: medical imaging equipment; a stand-alone radiological information system; and a breakaway interface disposed between the radiological information system and the medical imaging equipment. The Examiner's consideration of the same is respectfully requested.

With regard to claims 1-3, 5-9 and 29, the Examiner is referred first to the "Field of the Invention" on page 1 of the present specification, which states: "This invention pertains generally to computer-aided imaging systems and computer-aided radiological information systems. More specifically, the present invention incorporates image analysis and work order evaluation to ensure that a radiological information system and computer-aided imaging system produce desired and matched images and work orders in an automated and reliable manner." As the Examiner can ascertain therefrom, the present invention incorporates a combination of computer hardware and software to vastly enhance existing imaging systems.

Claim 1 recites four means, which are receiving, dividing, matching and transmitting means. For specific consideration of each of these means, the Examiner is referred first to page

11 of the specification, between lines 1 and 19, which states in relevant part: “Consequently, for the purposes of this disclosure, phrases such as coupling, transmitting, receiving and the like will be understood to include not only direct connection by local wiring, but also to other suitable communications, including but not limited to both physical and virtual interconnections including local area networks, wide area networks, Internet, radio and satellite communications, and so forth. Breakaway interface 140 includes means to receive the work lists, the means which are dependent upon the type of network or communications system in use and which includes all suitable known apparatus. **The reception means, for exemplary and not limiting purposes, may include such devices as network interface cards, modems, direct wiring or the like, typically associated with appropriate software or hardware for implementing the necessary function. The appropriate apparatus will be determined by those skilled in the art at the time of design. . . . Similar to the above mentioned reception means, breakaway interface 140 will include appropriate means for transmission, once again dependent upon the type of network or communications system, and once again determined by those skilled in the art at design time.**” (Emphasis added) At the time of filing, the applicants recognized that many diverse types of hardware or hardware in combination with software might be used to implement the various means and so has identified and taught a variety of such elements.

The means for dividing and the means for matching recited in claim 1 are found in step 300 of Figure 2, which is shown in much greater detail in Figure 3. From the specification beginning in line 16 of page 12 and ending in line 10 of page 13, the applicants state:

“In the event the image sequence was generated from a rationalized work list which was different from the work list received from radiological information system 110, breakaway interface 140 will include means to break images away from the image sequence received from imaging equipment 120 into smaller rationalized image sequences. **In the preferred embodiment, breakaway interface 140 intelligently applies algorithms to the images to determine the best way to split up the image sequence, as will be described in greater detail herein below with specific reference to figure 2.**

Once the smaller rationalized image sequences are derived from the larger sequence received from imaging equipment 120, breakaway interface 140 includes means to communicate the smaller rationalized image sequences to a

PACS system 130 or the like. Most preferably, the communications protocol will conform to DICOM standards, though this is not essential to the workings of the invention. **In addition to the transmission of the rationalized image sequences, the associations to rationalized work lists or HL-7 orders will also be transmitted, thereby ensuring proper one-to-one correspondence within PACS 130. The specific apparatus used will be selected by those skilled in the art from the myriad of available hardware and software combinations known in the art to be suitable for the communications required herein.”**
(Emphasis added)

In consideration of these references from the present specification, which identify each of the means that are recited in the claims identified by the Examiner, the Examiner is respectfully requested to reconsider the rejections of claims 1-3, 5-9 and 29 under 35 U.S.C. 112, second paragraph, and allow these claims to issue.

Non-Statutory Subject Matter under 35 U.S.C. 101

In paragraph 9 of the outstanding office action, the Examiner states in relevant part: “However, it is noted that the specification does not disclose any specific corresponding structure or equivalents thereof.” In contradiction therewith, from the foregoing section reproduced herein above under the section regarding 35 U.S.C. 112, second paragraph, the applicants identified a very substantial amount of hardware, software, and included many equivalents. The particular hardware, and any software that may be affiliated therewith as would be selected by a designer reasonably skilled in the art enabled by the present disclosure, combine to produce a statutory machine and process that performs useful function and novel benefit. The breakaway interface as disclosed and recited operates in combination with radiology accounting and billing information systems that have one-to-one correspondence between individual radiological studies and individual work orders and with picture archive and communication system (PACS) having one-to-one correspondence between individual radiological studies and individual work orders,

and with radiological imaging machines that produce multiple studies from a single work order. The present invention interfaces between these various prior art apparatus to produce a plurality of distinct image studies from a single imaging sequence by the radiological imaging machine. This breakaway interface which generates a plurality of image studies from a single imaging sequence is tied to the PACS, radiology accounting and billing, and radiological imaging apparatus and is therefore a part of that statutory subject matter, and also does transform the image sequence into a plurality of imaging studies which are different from the original sequence, thereby meeting not just one, but both of the ways to determine statutory subject matter that the Examiner references in paragraph 10. In consideration of the foregoing, the Examiner is respectfully requested to reconsider the outstanding rejection of claims 1-29 under 35 U.S.C. 101, and allow the present claims to issue.

The Prior Art

In the outstanding office action, the Examiner observes in the second paragraph of page 6: “The combination of Short/Sitka does not specifically disclose means for dividing said image sequence into separate, anatomically associated image sequences.” The Examiner relies upon Hilton et al to cure this deficiency, and states that “Hilton, however, in at least column 2, lines 40-47 discloses, “...each image group is partitioned into one or more ordered image series, each ordered image series including a succession of images which illustrate incrementally registered aspects of an anatomical target . . .” While at first blush this may sound similar to the present invention, further reading reveals that this feature is completely unrelated to the present invention. In column 8, between lines 37 and 56, Hilton et al identify what an “image group” actually is:

“For any patient identification entered in the file 50, its corresponding ROOTNAME points to an examination file such as the file 53, which is entitled ‘ROOTNAME.PAT’. Each examination file 53 identifies an image group including one or more image series obtained during an examination. Each image series in an image group is indexed to a set of sequentially named or numbered

files in which the images of the series are contained. **For example, in the ROOTNAME.PAT file 53 illustrated in FIG. 6, the image group includes axial T1, axial T2, and sagittal T1 series.** The axial T1 series consists of n consecutively-numbered files, each containing a respective image of the series such that the sequence position of the named file corresponds to the sequence position of the image it contains. The image files are named ROOTNAME.XXX. Thus, image 1 in the axial T1 series has a file name ROOTNAME.1, the second image in this series is in a file named ROOTNAME.2 and so on. Similarly, the n images of the axial T2 series are stored in files consecutively numbered as ROOTNAME.m through ROOTNAME.(m+n).”
(Emphasis added)

From the above Hilton et al text, it is apparent that the “image group” referred to in the excerpt cited by the Examiner is not a single image series that is later divided in any way into smaller series, but is instead a plurality of separately produced imaging series. In other words, the imaging apparatus would have executed three separate work orders to produce the axial T1, axial T2 and sagittal T1 series that the Hilton text refers to. This fact is immediately confirmed by the recognition that the axial series and sagittal series do not come from the same single scan. Hilton et al do not disclose any means for dividing an image sequence.

Short et al illustrate a similar system, as is evidenced by Figure 4, which also appears on the front page, as the exemplary figure, and from the text in paragraphs 22 - 25. Therein, a technician can select a multiple exam mode. When the technician selects this mode, in step 36: “Before each image is taken, technologist returns to workstation selects folder to place image into.” In step 44,: “At close exam, a pop-up appears notifying of any procedure without images.”

From the foregoing text, the Examiner will recognize that both Hilton et al and Short et al are very exemplary of the prior art that the present applicants have identified, wherein the radiology accounting and billing information system has a one-to-one correspondence between

individual radiological studies and individual work orders, and the picture archive and communication system has a one-to-one correspondence between individual radiological studies and individual work orders. Consequently, the radiological imaging machine must be run once for each study, even if as taught by the present invention the studies could have been produced in a single run by the radiological imaging machine.

The Present Invention

Contrary to Sitka et al, Hilton et al and Short et al, the present invention overcomes the need for one-to-one correspondence between work orders and radiological studies by providing a means for dividing the sequence into separate, anatomically associated image sequences. While independent claim 1 remains with the original text, the remaining independent claims 10, 18, and 28 are presently amended to incorporate alternative language for consideration by the Examiner. Each of the independent claims incorporate the limitation of dividing the sequence.

The present claims recite further novel combinations of automated processing, affiliating work orders into super orders, and novel methods of analysis for which applicants respectfully request consideration by the Examiner. In the outstanding office action, the Examiner acknowledges that the particular methods of analysis used to divide image sequences recited by the claims, such as claims 5 - 7 for example, are not found in the references of record. The Examiner, in rejecting these claims, "takes official notice that it is old and well-known in the imaging arts to segment images by using" the particular methods recited by the applicants in the claims. The applicants disagree.

Each of the recited techniques are known in the graphics industry, as noted in the present specification on page 16 in lines 5 - 7. However, the recognition that these techniques may be used to divide anatomical images into anatomically relevant sequences is new in the radiology art to which the present invention pertains. As the present specification notes on page 12 in lines 19 - 22: "In the preferred embodiment, breakaway interface 140 intelligently applies algorithms to the images to determine the best way to split up the image sequence" In the prior art of record, there has not even been a consideration of dividing the image sequence, much less the

particular beneficial techniques identified and specifically enumerated by the present applicants. Reconsideration of the patentability of these additional claims is therefore respectfully requested.

In further support of the novelty of the present invention, several affidavits are presented herewith by individuals with significant experience and expertise in the field of radiological imaging. Consideration of these affidavits, and the further support they provide regarding the novelty of the present invention, is respectfully requested.

The features recited by the present claims are not found in, nor taught by, any of the references of record. In view of the recitations in these independent claims, and the absence of the features or teachings thereto in the prior art, the Examiner is respectfully requested to reconsider the rejection and pass this application to allowance. No new matter has been introduced in the present amendment.

It appears that all matters have been addressed satisfactorily, and that the case is now in condition for a complete allowance; and the same is respectfully urged.

However, if the Examiner has any comments or questions, or has any suggestions as per MPEP 707.07 (d) and (j), for putting the case in condition for final allowance, he is respectfully urged to contact the attorney of record, Mr. Leonard Bloom, at 410-769-6144, so that an expeditions resolution may be effected and the case passed to issue promptly.

Respectfully Submitted,

A handwritten signature in cursive script, reading "Leonard Bloom", is written over a horizontal line.

Date

Leonard Bloom

Reg. No. 18,369

Attorney for Applicants

Enc.

Serial No. 10/667,947
Docket No. 02358-PA

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: DeJarnette Research Systems, Inc.

Application Serial No. 10/667,947

Filed: 09/22/2003

For: BREAKAWAY INTERFACING OF RADIOLOGICAL IMAGES WITH WORK ORDERS

AFFIDAVIT OF ABE NADER

I, Abe Nader, solemnly swear or affirm as follows:

1. I am the PACS Coordinator of Inova Fairfax Hospital. I have occupied this position for 5 years. I have specialized in the field of radiological imaging for 11 years.
2. I have been using the Applicant's product, which is the working model of the above-referenced patent application, since 2004.
3. Applicant's product is the only product available that automates a radiological technologist's manual procedures. That is, in doing a multiple body part CT scan, a technologist has to group the acquired images into body part groups prior to review because radiologists need to focus on one body part study at a time. Generally, CT scanners acquire imaging data from the head down, in linear fashion. However, radiologists do not review the studies the same way; a radiologist, for example, may wish to review a scan of the pelvis first, and then of the chest, or a specialist may only wish to see the images of a specific body part. The manual process requires the assistance of a radiological technologist to organize and present the studies to the radiologist according to the diagnostic orders. With Applicant's product, the radiologist and technologist do not have to manually sort the studies. This frees the radiologist up for reviewing the studies as presented by Applicant's product and frees the technologist up to do scans. Since our

profitability is based on volume of scans performed and reviewed, Applicant's product has helped us increase our productivity since we began using it.

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment under federal law, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting there from, declares that all statements made of his/her own knowledge are true; based on personal knowledge; and all statements made on information and belief are believed to be true.

DATE: 5/5/09

A handwritten signature in black ink, appearing to read 'Abe Nader', with a long horizontal flourish extending to the right.

Abe Nader

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: DeJarnette Research Systems, Inc.

Application Serial No. 10/667,947

Filed: 09/22/2003

For: BREAKAWAY INTERFACING OF RADIOLOGICAL IMAGES WITH WORK ORDERS

AFFIDAVIT OF DAVID BOWEN

I, David Bowen, solemnly swear or affirm as follows:

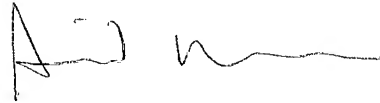
1. I am the Imaging Systems Manager of Barts and The London NHS Trust (London). I have recently occupied this position but have been employed by the organization for four years. I have specialized in the field of radiological imaging for 7 years (including training).
2. I have been using the Applicant's product, which is the working model of the above-referenced patent application, since 2007.
3. Applicant's product is the only product available that automates a radiological technologist's manual procedures. That is, in doing a multiple body part CT scan, a technologist has to group the acquired images into body part groups prior to review because radiologists need to focus on one body part study at a time. Generally, CT scanners acquire imaging data from the head down, in linear fashion. However, radiologists do not review the studies the same way; a radiologist, for example, may wish to review a scan of the pelvis first, and then of the chest, or a specialist may only wish to see the images of a specific body part. The manual process requires the assistance of a radiological technologist to organize and present the studies to the radiologist according to the diagnostic orders. With Applicant's product, the radiologist and technologist do not have to manually sort the studies. This frees the radiologist up for reviewing the studies as presented by Applicant's product and frees the technologist up to do scans. Since our

profitability is based on volume of scans performed and reviewed, Applicant's product has helped us increase our productivity since we began using it.

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment under federal law, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting there from, declares that all statements made of his/her own knowledge are true; based on personal knowledge; and all statements made on information and belief are believed to be true.

DATE: 7th May 09

DAVID BOWEN
[Print Name]

A handwritten signature in dark ink, appearing to read 'David Bowen', written over a horizontal line.

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: DeJarnette Research Systems, Inc.

Application Serial No. 10/667,947

Filed: 09/22/2003

For: BREAKAWAY INTERFACING OF RADIOLOGICAL IMAGES WITH WORK ORDERS

AFFIDAVIT OF STEVEN R. ROBERTS

I, Steven R Roberts, solemnly swear or affirm as follows:

1. I am the Manager, Open Systems Administration of SUNY Upstate Medical University. I have occupied this position for 6 years. I have specialized in the field of radiological imaging (PACS) for 6 years.
2. I have been using the Applicant's product, which is the working model of the above-referenced patent application, since 2004.
3. Applicant's product is the only product available that automates a radiological technologist's manual procedures. That is, in doing a multiple body part CT scan, a technologist has to group the acquired images into body part groups prior to review because radiologists need to focus on one body part study at a time. Generally, CT scanners acquire imaging data from the head down, in linear fashion. However, radiologists do not review the studies the same way; a radiologist, for example, may wish to review a scan of the pelvis first, and then of the chest, or a specialist may only wish to see the images of a specific body part. The manual process requires the assistance of a radiological technologist to organize and present the studies to the radiologist according to the diagnostic orders. With Applicant's product, the radiologist and technologist do not have to manually sort the studies. This frees the radiologist up for reviewing the studies as presented by Applicant's product and frees the technologist up to do scans. Since our

profitability is based on volume of scans performed and reviewed, Applicant's product has helped us increase our productivity since we began using it.

The undersigned being warned that willful false statements and the like are punishable by fine or imprisonment under federal law, and that such willful false statements and the like may jeopardize the validity of the application or document or any registration resulting there from, declares that all statements made of his/her own knowledge are true; based on personal knowledge; and all statements made on information and belief are believed to be true.

DATE: 5/8/09

STEVEN R. ROBERTS
[Print Name]

BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: DeJarnette Research Systems, Inc.

Application Serial No. 10/667,947

Filed: 09/22/2003

For: BREAKAWAY INTERFACING OF RADIOLOGICAL IMAGES WITH WORK ORDERS

AFFIDAVIT OF WAYNE DEJARNETTE

I, Wayne DeJarnette, solemnly swear or affirm as follows:

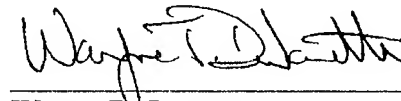
1. I am the president and chief executive officer of DeJarnette Research Systems, Inc. I have occupied this position for 24 years. I have specialized in the field of radiological image processing for 30 years.

2. DeJarnette Research Systems, Inc. has sold 64 licenses for the referenced invention to 23 individual medical treatment facilities. Total sales volume to date for the referenced invention is approximately \$1.6 million.

3. The licensees for the referenced invention have performed an aggregate of over a half million image studies.

4. I am not aware of any similar products in the North American, European, or Asian markets. If there were any similar products, I would be aware of them.

DATE: 4/1/2009



Wayne DeJarnette